

EXHIBIT B

Case 2:21-cv-10312-SJM-RSW ECF No. 1, PageID.1 Filed 02/10/21 Page 1 of 8

1 **IN THE UNITED STATES DISTRICT COURT**
2 **EASTERN DISTRICT OF MICHIGAN**

3
4 Stanley H. Kremen,
5 Attorney at Law
6 4 Lenape Lane
6 East Brunswick, New Jersey 08816
7 (732) 593-7294
7 Attorney for the Plaintiff

SOUTHERN DIVISION

TRUTEK CORP.,

Case No. 2:21-cv-10312

Plaintiff,

Hon. Stephen J. Murphy, III

v.

BlueWillow Biologics, Inc.
ROBIN ROE 1 through 10, gender neutral fictitious
names, and ABC CORPORATION 1 through 10
(fictitious names).

BLUEWILLOW BIOLOGICS, INC.,
et. al.

Defendants.

PLAINTIFF TRUTEK CORPORATION'S
AMENDED COMPLAINT

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CIVIL ACTION No. _____

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15 **COMPLAINT**16
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18 **DEMAND FOR JURY TRIAL**19
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NOW COMES Plaintiff, TRUTEK CORP., by and through its attorneys, the Law Office of Stanley H. Kremen and The Law Office of Keith Altman, and for their Amended Complaint, hereby states the following:

PARTIES

19 Plaintiff, TRUTEK CORP. ("TRUTEK") is a corporation of the State of New Jersey, with principal offices at 281 East Main Street, Somerville, New Jersey, 08876.

20 Upon information and belief, Defendant, BlueWillow Biologics, Inc. ("BLUEWILLOW") is a corporation of the State of Delaware, with a place of business at 2311 Green Road, Suite A, Ann Arbor, Michigan 48105.

FEDERAL SUBJECT MATTER JURISDICTION

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26 3. The subject matter jurisdiction of this
Court arises under 28 U.S.C. § 1331

27 concerning a federal question, the Patent Laws
of the United States, 28 U.S.C. §§

28 3. 1338(a), (b), and 35 U.S.C. § 271.

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 2

IN PERSONAM JURISDICTION

4. 4. The *in personam* jurisdiction of this Court over Defendant BLUEWILLOW is proper under 28 U.S.C. § 1400(b) because the tort of patent infringement occurred in Michigan and BLUEWILLOW has an established place of business in Michigan.

7. #

VENUE

9. 5. The venue of this Court is proper under the Patent Venue Statute, 28 U.S.C. § 1400(b) since the tort of patent infringement occurred within the State of Michigan, and Defendant BLUEWILLOW has an established place of business thereat, and which is furthermore located within the venue of the Eastern District of Michigan.

13. #

STATEMENT OF FACTS AND CAUSES OF ACTION

15. 6. Ashok Wahi ("WAHI") is PresidentChief Science and IP Officer of Plaintiff TRUTEK.

16. 7. On November 21, 1995, United States Patent No. 5,468,488 (hereinafter the '488

18. Patent) was issued to WAHI for his invention titled, "Electrostatically Charged

20. 7. Nasal Application Product and Method." The '488 Patent was assigned to TRUTEK.

21. 8. On October 7, 1997, United States Patent No. 5,674,481 (hereinafter the '481

22. 8. Patent) was issued to WAHI for his invention titled, "Electrostatically Charged Nasal Topical Application Product." The '481 Patent was assigned to TRUTEK.

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24 9.—On January 18, 2005, United States Patent No. 6,844,005 (hereinafter the
 25 '005
 26 9. Patent) was issued to WAHI for his invention titled, "Electrostatically Charged Nasal
 27 Application Product With Increased Strength." The '005 Patent was assigned to
 28 TRUTEK.

29 40.—On April 24, 2012, United States Patent No. 8,163,802 (hereinafter the '802
 30 Patent) was issued to WAHI for his invention titled, "Electrostatically
 31 Charged
 32 ~~Case 2:21-cv-10312-SJM-RSW ECF No. 1, PageID.3 Filed 02/10/21 Page 3 of 8~~

33
 34 10. Multi-Acting Nasal Application Product, and Method," on a patent application that
 35 was filed at the United States Patent and Trademark Office (USPTO) on May 16,
 36 2009. The '802 Patent was assigned to TRUTEK. The '802 Patent is attached hereto
 37 as Exhibit 6.

38 11. The patented technology made it possible for people to apply TRUTEK's
 39 manufactured products in and around their nasal passages to reduce reactions to
 40 airborne allergens and to reduce or eliminate reactions to viral infections from
 41 influenza and the common cold by restricting and inactivating virus sized particles.
 42 This is done by establishing an electrostatic charge in and around nasal passages.

43 42.—As of the year 1992 going forward, TRUTEK utilized its patented and
 44 proprietary trade secret technology to establish proof of concept, develop,
 45 formulate, manufacture, sell, and/or license over-the-counter products under
 46 the brand name

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47 NasalGuard® AllergieBlock®, NasalGuard Cold&Flu Block®, NasalGuard®
 48 Multi Acting™, Anti-Stat Enhanced Mask™, NasalGuard Wipes™,
 49 NasalGuard Allergie

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50 Wipes™, NasalGuard Cold & Flu Wipes™, Skin and Hair super
 51 conditioners, Truteks® Skin and Truteks® skin care products, along with
 52 electrostatically charged nasal multipurpose products, nasal application (anti-
 53 stat) diagnostic products and, associated Technologies and Methodologies,
 54 Patents and Pending

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55 Patent Applications, also including products under the brand names
 56 Chloraseptic

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57 12. Allergen Block and Little Allergies Allergen Block, Eisai Crystal Veil, Eisai Crystal
 58 Veil Cool, Nitto Nuru Mask, Nitto NasalGuard, further including but not limited to
 59 nasal application product lines such as gels, pre-moistened products for *e.g.*
 60 applicators, swabs, wipes, etc., sticks, nasal sprays, nasal washes, surgical masks, and
 61 multi-acting/integrated products.

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62 13. Claim 1 of the '802 Patent claims a method of applying a formulation to the skin
 63 or tissue of a person's nasal passages in a thin film. The formulation attracts
 64 and holds particulate matter to the thin film, and binds it to the thin film. The
 65 bound

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68 13. particulate matter is then inactivated by at least one ingredient that renders it harmless.¶

69 One such claimed inactivating ingredient is benzalkonium chloride (claim 7). This
70 process is sometimes referred to as "catch, hold, and kill."¶

71 14.Claim 2 of the '802 Patent claims a formulation that is applied to the skin or tissues
72 of a person's nasal passages in a thin film. The formulation contains a cationic agent
73 (an ingredient that produces a positive electrostatic charge) and a biocidic agent (a
74 substance that destroys or inhibits the growth or activity of living organisms). The
75 formulation electrostatically attracts and holds particulate matter to the thin film, and
76 binds it to the thin film. The bound particulate matter is then inactivated by at least
77 one ingredient that renders it harmless. One such claimed cationic agent is
78 benzalkonium chloride (claim 6) and one such claimed biocidic agent is benzalkonium
79 chloride (claim 7). This formulation functions using the process referred to as "catch,
80 hold, and kill," supra.

BLUEWILLOW'S Nanobio® Protect Products

81 44-15. According to information and belief, sometime in 2020, Defendant
82 BLUEWILLOW manufactured and marketed one or more over-the-counter
83 pharmaceutical products named NanoBio® Protect ("NANOBIO"). According to
84 information and belief, the NANOBIO products were sold over-the-counter at least at
85 CVS pharmacies nationwide, and were sold online to customers by Amazon.com.¶

86 45-16. BLUEWILLOW's website advertises the NANOBIO product being applied to a
87 customer's nasal passages. Their product forms positively charged "NanoBio

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89 "Droplets" that are approximately 600 nanometers¹ in size, which adhere to nasal
 90 membranes. Most harmful particles, such as bacteria or viruses (referred to as
 91 "germs"), are negatively charged. The positively charged "NanoBio Droplets" attract
 92 and bind to these particles. The NANOBIO product formulation contains
 93 benzalkonium chloride (which the website calls BZK) that adheres to the surface of
 94 the "NanoBio droplets." According to the website, the "NanoBio droplets" surround
 95 the germs and "kill them via membrane disruption." (See Exhibit 1 attached hereto.)
 96 The NANOBIO product implements the methodology of "catch, hold, and kill." The
 97 NANOBIO website "Frequently Asked Questions" section (Exhibit 2) describing the
 98 product further enforces this mechanism of action.

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99 ~~16.~~^{17.} Sometime in 2020, WAHI suspected that the NANOBIO product infringes one or
 100 more of TRUTEK's patents. To that end, on June 23, 2020, TRUTEK personnel
 101 purchased the NANOBIO product from Amazon.com. After extensive in-house
 102 experimentation, it was indicated that the NANOBIO product functions by producing
 103 an electrostatic charge in and around the user's nasal passages. It was indicated that
 104 NANOBIO product infringes claims of TRUTEK's '802 Patent. On January 14, 2021,
 105 TRUTEK personnel purchased a NANOBIO product from CVS, and obtained similar
 106 results through in-house experimentation.

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107 On January 14, 2021, TRUTEK personnel purchased a NANOBIO product from
 108 Case 2:21-cv-10312-SJM-RSW ECF No. 1, PageID.5 Filed 02/10/21 Page 5 of 8

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¹ A nanometer is a billionth of a meter.

109
110 ~~CVS, and obtained similar results through in-house experimentation.~~

111 17. To validate TRUTEK's in-house experimental results, TRUTEK contracted with
112 ~~Alexei Alexei~~ Ermakov, Ph.D. to compare the electrostatic charges between
113 BLUEWILLOW's NANOBIO product and TRUTEK's NasalGuard®
114 products. His experiments showed not only that the NANOBIO product
115 exhibited a surface electrostatic charge, but also that the orders of magnitude
116 of the charges of the

117 BLUEWILLOW and TRUTEK products were of the same order of
118 magnitude. Dr.

119 Ermakov's Report is attached hereto as Exhibit 3. For further verification,

120 ~~TRUTEK contracted with Electro-Tech Systems ("ETS") in Perkasie,~~

121 18. Pennsylvania, to run additional experiments. ETS personnel applied
122 BLUEWILLOW's NANOBIO product and TRUTEK's NasalGuard® product to pig
123 skin swatches. Pig skin is very similar to human skin tissue. The ETS and Ermakov
124 experiments yielded similar results. The NANOBIO product exhibited a surface
125 electrostatic charge of the same order of magnitude as the NasalGuard® product. The
126 ETS report is attached hereto as Exhibit 4.

127 48. On January 31, 2021, Keith Altman, a resident of the State of Michigan,
128 ordered and paid for one unit of NanoBio Protect Nasal Antiseptic online
129 from

130 Amazon.com. The product was to be shipped by Amazon.com to his address
131 in Michigan. Mr. Altman used his computer to place the order, and the

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132 computer is located in Michigan, and it was located therein at the time that he
 133 placed his order. On February 1, 2021, Mr. Altman received the ordered one
 134 unit of NanoBio

135 19.Protect Nasal Antiseptic in Michigan at the designated Michigan shipping address. A

136 declaration of Keith Altman attesting to these events is attached hereto as Exhibit 5.

137 49.20.The ability to lessen the reactions to airborne contaminants by creating an
 138 electrostatic charge around a person's nasal passages was disclosed in TRUTEK's
 139 '488, '481, '005, and '802 Patents. A copy of the '802 Patent is attached hereto as
 140 Exhibit 6.

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143 20.21.The ability to lessen the reactions to airborne contaminants by creating an
 144 electrostatic charge around a person's nasal passages is inherent in TRUTEK's
 145 formulations and manufacturing processes. Efficacy studies show that TRUTEK's
 146 methodology presented a viable solution to relief of allergy, cold, and flu symptoms.

147 21.22.Upon information and belief, just as TRUTEK's products work on allergens and
 148 viruses by creating an electrostatic charge around nasal passages and further inactivate
 149 said allergens and viruses, the NANOBIO products work the same way.

150 23.At some point after this lawsuit was filed, BLUEWILLOW discontinued sales of the
 151 NANOBIO products, and the product descriptions were removed from
 152 BLUEWILLOW'S website.

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153 ~~22~~²⁴. The NANOBIO products ~~are were~~ sold to customers by Amazon.com as are
 154 TRUTEK's competing products also sold thereby. The competitive sales of the
 155 competing NANOBIO products deprive TRUTEK of sales and profits from its own
 156 products.

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157 ~~23~~—Upon information and belief, Defendants Robin Roe 1 through 10 and ABC

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158 ~~25~~ Corporations 1 through 10 also infringe on the claims of TRUTEK's '802 Patent.

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159 #

WILLFUL PATENT INFRINGEMENT

162 Plaintiff owns intellectual property relating to an electrostatically charged multi-
 163 acting nasal application product and method covered by the '802 patent.

164 Defendants distributed, made, used, offered to sell and/or sold infringing products,
 165 *i.e.*, the NANOBIO products.

166 Defendants distributed, made, used, offered to sell and/or sold infringing products,
 167 *i.e.*, the NANOBIO products, which infringe on the '802 patent, without authority or
 168 license from Plaintiff.

169 Defendants infringe at least claims 1, 2 and 7 of the '802 patent because the
 170 NANOBIO products possess an electrostatic charge when applied to a person's nasal
 171 passages, and they use benzalkonium chloride as a cationic agent and also as a biocidic
 172 agent.

173 30. Defendants received notice that the NANOBIO products infringed on claims 1, 2, 6
 174 and 7 of the '802 patent when Plaintiff filed the original complain in this action on
 175 February 10, 2021.

176 31. Defendants had knowledge of the '802 patent on the date of the original complaint in
 177 the present action.

178 32. Defendants continued to market, distribute, and sell NANOBIO products for
 179 approximately months after learning that the NANOBIO products infringed on claims
 180 1, 2, 6 and 7 of the '802 patent. A copy of BlueWillow Biologics, Inc.'s, financial
 181 records are attached hereto as Exhibit 7.

182 33. Defendants provided Plaintiff with copies of BlueWillow Biologics, Inc.'s, financial
 183 records after the close of discovery.

184 34. Plaintiff has analyzed BlueWillow Biologics, Inc.'s financial records, and the records
 185 establish by a preponderance of the evidence that enhanced damages are appropriate.

186 35. Defendants' actions constitute willful patent infringement under 35 U.S.C. § 284 and
 187 35 U.S.C. § 285.

188 36. Under 35 U.S.C. § 284, when the damages are not found by a jury, the court shall
 189 assess them; in either event the court may increase the damages up to three times the
 190 amount found or assessed.

191
 192 **GENERAL ALLEGATIONS**

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193 ~~24~~³⁷. Plaintiff incorporates all of the above Paragraphs *supra* as though fully restated
 194 herein.

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195 ~~25~~³⁸. Plaintiff owns intellectual property related to certain formulations based upon
 196 attracting and/or repelling electrostatically charged particles in and around a person's
 197 nasal passages by application of a product that maintains an electrostatic charge on
 198 the skin or mucous membranes. Plaintiff has expended considerable resources to
 199 inventing, formulating, and developing its inventions and products and to protecting
 200 its rights therein. Plaintiff holds all rights, title, and interest to its '488, '481, '005, and
 201 '802 Patents. The '802 Patent is in full force and effect. TRUTEK is the legal owner
 202 of the '802 Patent and possesses all rights of recovery under the patent.

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208 STATEMENT OF CLAIMS

209 COUNT 1

210 Infringement of the '802 Patent

211 ~~26~~³⁹. Plaintiff incorporates all of the above Paragraphs *supra* as though fully restated
 212 herein.

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213 ~~27~~⁴⁰. Plaintiff owns intellectual property relating to an electrostatically charged
 214 ~~multiacting~~^{multi-acting} nasal application product and method covered by the '802
 215 patent.

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216 ~~28~~⁴¹. Defendants ~~distribute, make, use, offer~~^{distributed, made, used, offered} to sell and/or
 217 ~~sellsold~~ infringing products, *i.e.*, the NANOBIO products.

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218 ~~29~~⁴². Defendants ~~distribute, make, use, offer~~^{distributed, made, used, offered} to sell and/or
 219 ~~sellsold~~ infringing products, *i.e.*, the NANOBIO products, which ~~infringe~~^{infringed} on
 220 the '802 Patent, without authority or license from Plaintiff.

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221 ~~30~~⁴³. Defendants infringe at least claims 1, 2, and 7 of the '802 Patent because the
 222 NANOBIO products possess an electrostatic charge when applied to a person's nasal
 223 passages, and they use benzalkonium chloride as a ~~biocide~~^{cationic agent} and also as a
 224 ~~biocidic agent~~.

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225 ~~31~~⁴⁴. Plaintiff has been damaged as a result of Defendants' infringement of the '802
 226 Patent, and will continue to be damaged unless such infringement is enjoined by this
 227 Court pursuant to 35 U.S.C. § 283.

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228 ~~32~~⁴⁵. Pursuant to 35 U.S.C. § 284, Plaintiff is entitled to damages adequate to
 229 compensate in an amount not less than a fair and reasonable royalty.

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230 ~~46~~^{Alternatively, as the NANOBIO products are no longer being sold by Defendants,}
 231 ~~Plaintiff is entitled to damages adequate to compensate in an amount not less than the~~
 232 ~~profits realized by Defendants for past sales of the NANOBIO products.~~

233 47. Pursuant to 35 U.S.C. § 284, Plaintiff is entitled to damages adequate to compensate
234 in an amount not less than a fair and reasonable royalty.

235 48. Plaintiff is entitled to a judgment from the Court, which enjoins sales or
236 commercialization by BLUEWILLOW of its NANOBIO products until after
237 expiration of the ‘802 Patent.

238 **COUNT 2**

239 **Willful Infringement of the ‘802 Patent**

240 49. Plaintiff incorporates all of the above paragraphs *supra* as though fully restated herein.

241 50. Plaintiff owns intellectual property relating to an electrostatically charged multi-
242 acting nasal application product and method covered by the ‘802 patent.

243 51. Defendants distributed, made, used, offered to sell and/or sold infringing products,
244 i.e., the NANOBIO products.

245 52. Defendants distributed, made, used, offered to sell and/or sold infringing products,
246 i.e., the NANOBIO products, which infringe on the ‘802 patent, without authority or
247 license from Plaintiff.

248 53. Defendants infringe at least claims 1, 2, 6, and 7 of the ‘802 patent because the
249 NANOBIO products possess an electrostatic charge when applied to a person’s nasal
250 passages, and they use benzalkonium chloride as a cationic agent and also as a biocidic
251 agent.

252 54. Under 35 U.S.C. § 284, when the damages are not found by a jury, the court shall
 253 assess them; in either event the court may increase the damages up to three times the
 254 amount found or assessed.

255 55. Defendants had knowledge of the '802 patent on the date of the original complaint in
 256 the present action.

257 56. Defendants continued to market, distribute, and sell NANOBIO products for months
 258 after learning that the NANOBIO products infringed on claims 1, 2, 6, and 7 of the
 259 '802 patent.

260 57. Defendants' actions and financial records demonstrate that Defendants' conduct
 261 amounted to intentional or knowing infringement of the 802' patent.

262 58. Defendants' actions constitute willful patent infringement under 35 U.S.C. § 284 and
 263 35 U.S.C. § 285.

264 59. Pursuant to 35 U.S.C. § 285, the court in exceptional circumstances may award
 265 reasonable attorneys' fees to the prevailing party.

267 **PRAYER FOR RELIEF**

268 Wherefore, Plaintiff prays that:

269 4.a) Defendants be required to pay over and account to Plaintiff for all
 270 gains, profits, and advantages derived from the infringement of its '802
 271 Patent beginning April 24, 2012, based upon manufacture, sales, and/or use

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of the NANOBIO products in the United States and anywhere in the world,
or by way of international commerce with the United States.

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274 2. Defendants be enjoined from manufacturing and/or selling the NANOBIO
275 b) products in the United States, either directly or indirectly.

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c) ~~13.~~ Defendants be enjoined from actively inducing others to sell the

NANOBI~~O~~ products in the United States, either directly or indirectly.

~~34. Defendants be enjoined from exporting the NANOBI~~O~~ products from the United States, either directly or indirectly.~~

5 Plaintiff prays for such other and further relief as the Court may deem to be just

~~6d)~~ and proper.

~~7 H~~

8 DEMAND FOR DISCOVERY OF INSURANCE COVERAGE

9 Pursuant to Defendants' discovery obligations, demand is made that all

10 Defendants disclose to the Plaintiff whether or not there are any insurance agreements

11 or policies under which any person or firm carrying on an insurance business may be

12 liable to satisfy part or all of a judgment which may be entered in this action or indemnify

13 or reimburse for payments made to satisfy the judgment and provide Plaintiff with true

14 copies of those insurance agreements or policies, including, but not limited to, any and

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45 all declarations sheets. This demand shall include and cover not only primary

coverage, ~~46~~ but also any and all excess, catastrophe and umbrella policies.

47 *H.*

48 **DEMAND FOR A JURY TRIAL**

49 Plaintiff hereby demands a trial by jury of all issues triable of right by

a jury.

20 Dated: February 9, 2021 October 25, 2022

Respectfully

21

/s/ Stanley H. Kremen

22 Stanley H. Kremen, Esq.

Attorney for Plaintiff

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Attorneys for Plaintiff, Trutek Corp.

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